1652

PATENT
Attorney Docket No. 01017/35966A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Han *et al.*

Serial No.: 09/724,126

Filed: November 28, 2000

For: The Human E3α Ubiquitin Ligase Family

Group Art Unit: 1652

Examiner: E. Slobodyansky

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:

June 20, 2003

#20
7/7/03

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Reg. No. 53,066
Agent for Applicants

INTERVIEW SUMMARY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.133 and M.P.E.P. § 713.04, Applicant submits this interview summary to reflect the substance of a telephonic interview on May 21, 2003, addressing the above-referenced application. Present at the interview were Examiner Slobodyansky and Applicant's representatives, William K. Merkel (Reg. No. 40,725) and Lynn L. Janulis (Reg. No. 53,066). Examiner Slobodyansky discussed with the Applicant's representatives the substance of the amendments attached in Appendix A, as summarized below.

During the telephonic interview, the Examiner indicated that amending claims 2 and 3 to recite an activity limitation along with a percent identity would warrant favorable consideration if supported by the specification and if there were no interfering art; however, the Examiner indicated that she would not consider allelic or splice variants. Further, the Examiner requested an amendment to part e) of claim 3 to have a close-ended range, for example "one to 100," and suggested that the Applicant confirm that "complementary," as recited in part f) of claim 3, was adequately defined in the specification.

In addressing fragment-based subject matter, the Examiner indicated that favorable consideration would be given to a claim to a fragment that is 100 amino acids less than the full-length sequence, if supported in the specification. Further, a claim drawn to the single nucleotide polymorphism that is taught in the application (see SEQ ID NO: 18 and new claim 65 in the amendment) was discussed.

The Examiner also indicated that claims 4-8 and claims 10-11 would be favorably considered if the relevant base claims from which they depend were appropriately amended. Also, removal of the phrase "and a pharmaceutical agent . . ." from claim 46 and revision of the language in claims 4, 46, and 48 to state "any one of claims 1, 2, or 3" were indicated by the Examiner as potentially receiving favorable treatment.

With respect to pending claim 59 and claims 60-64 dependent thereon, the Examiner indicated that an amendment to claim 59 to remove allelic or splice variants would result in favorable reconsideration of claims 59-64.

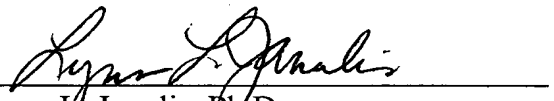
During the interview, the Examiner requested that "human E3α ubiquitin ligase" be written in full on its initial recitation in the claims; compliance with the request is reflected in the claim set attached as Appendix A . The Examiner also requested clarification of the meaning of "human E3α ubiquitin ligase activity," such as by citing to appropriate explanations in the specification. During the interview, Applicant's representatives identified passages in the specification, notably at page 2, line 8 to page 4, line 14, that provided a description of the function, or activity, of E3 ubiquitin ligase.

CONCLUSION

The Applicant submits that the substance of the interview is reflected in this summary. If further discussion would expedite allowance of the claims, the undersigned representative can be contacted at the telephone number indicated below.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN

By 

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APPENDIX A

CLAIM AMENDMENTS

1. (Thrice Amended) An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

(a) the nucleotide sequence as set forth in SEQ ID NO: 1;

(b) a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 2; and

(c) a nucleotide sequence complementary to either of (a) or (b).

2. (Thrice Amended) An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a polypeptide that is at least ~~95~~ 90 percent identical to the polypeptide set forth in SEQ ID NO: 2, wherein the encoded polypeptide has at least 1,649 amino acids and has human E3α ubiquitin ligase activity of the polypeptide set forth in SEQ ID NO: 2; and

(b) ~~a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence as set forth in SEQ ID NO: 1, encoding a polypeptide that has human E3α ligase activity of the polypeptide set forth in SEQ ID NO: 2;~~

~~(c)~~ a nucleotide sequence complementary to ~~any of~~ (a) ~~(b)~~.

3. (Thrice Amended) An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a polypeptide set forth in SEQ ID NO: 2 with ~~at least~~ a substitution of one to 100 conservative amino ~~acid~~ acids ~~substitution~~, wherein the polypeptide has human E3α ubiquitin ligase activity of the polypeptide set forth in SEQ ID NO: 2;

(b) a nucleotide sequence encoding a polypeptide set forth in SEQ ID NO: 2 with ~~at least~~ an insertion of one to 100 amino ~~acid~~ acids ~~insertion~~, wherein the

polypeptide has human E3α ubiquitin ligase activity of the polypeptide set forth in SEQ ID NO: 2, and optionally comprises a truncation and/or deletion up to about 100 amino acids;

(c) a nucleotide sequence encoding a polypeptide set forth in SEQ ID NO: 2 with ~~at least~~ an internal deletion of one to 100 amino ~~acid~~ acids ~~deletion~~, wherein the polypeptide has human E3α ubiquitin ligase activity of the polypeptide set forth in SEQ ID NO: 2;

(d) a nucleotide sequence encoding a polypeptide set forth in SEQ ID NO: 2 which has a C- and/or N-terminal truncation up to about 100 amino acids, wherein the polypeptide has human E3α ubiquitin ligase activity of the polypeptide set forth in SEQ ID NO: 2;

(e) a nucleotide sequence encoding a polypeptide set forth in SEQ ID NO: 2 with ~~at least~~ a modification of one to 100 amino acids ~~modification~~ selected from the group consisting of amino acid substitutions, amino acid insertions, amino acid deletions, C-terminal truncation, and N-terminal truncation, wherein the polypeptide has human E3α ubiquitin ligase activity of the polypeptide set forth in SEQ ID NO: 2; and

(f) a nucleotide sequence complementary to any one of (a)-(e).

4. (Amended) A vector comprising the nucleic acid molecule of any one of claims 1, 2, or 3.

5. (Original) A host cell comprising the vector of claim 4.

6. (Original) The host cell of claim 5 that is a eukaryotic cell.

7. (Original) The host cell of claim 5 that is a prokaryotic cell.

8. (Amended) A process of producing a ~~huE3α~~ human E3α ubiquitin ligase polypeptide comprising culturing the host cell of claim 5 under suitable conditions to express the polypeptide~~, and optionally isolating the polypeptide from the culture~~.

10. (Amended) The process of claim 8, wherein the nucleic acid molecule comprises promoter DNA other than the promoter DNA for the native ~~huE3α~~ human E3α ubiquitin ligase polypeptide operatively linked to the DNA encoding the ~~huE3α~~ human E3α ubiquitin ligase polypeptide.

11. (Original) The isolated nucleic acid molecule according to claim 2 wherein the percent identity is determined using a computer program selected from the group consisting of GAP, BLASTP, BLASTN, FASTA, BLASTA, BLASTX, BestFit, and the Smith-Waterman algorithm.

46. (Amended) A composition comprising a nucleic acid molecule of any one of claims 1, 2, or 3 ~~and a pharmaceutically acceptable formulation agent~~.

47. (Original) A composition of claim 46 wherein said nucleic acid molecule is contained in a viral vector.

48. (Amended) A viral vector comprising a nucleic acid molecule of any one of claims 1, 2, or 3.

59. (Thrice Amended) A reagent comprising a detectably labeled polynucleotide ~~encoding the amino acid sequence set out in SEQ ID NO: 2; or allelic variants or splice variants thereof with human E3α ligase activity~~ according to any one of claims 1 to 3.

61. (Twice Amended) A method for determining the presence of ~~huE3α~~ a human E3α ubiquitin ligase nucleic ~~acids~~ acid in a biological sample comprising the steps of:

(a) providing a biological sample suspected of containing ~~huE3α~~ a human E3α ubiquitin ligase nucleic ~~acids~~ acid;

(b) contacting the biological sample with ~~a~~ the reagent according to claim 59 under conditions wherein the reagent will hybridize with ~~huE3α~~ a human E3α ubiquitin ligase nucleic ~~acids~~ acid contained in said biological sample;

(c) detecting hybridization between ~~huE3α~~ the human E3α ubiquitin ligase nucleic acid in the biological sample and the reagent; and

(d) comparing the level of hybridization between the nucleic acid in the biological sample and the reagent with the level of hybridization between a known concentration of ~~huE3α~~ human E3α ubiquitin ligase nucleic acid and the reagent.

62. (Twice Amended) A method for detecting the presence of ~~huE3α~~ a human E3α ubiquitin ligase nucleic ~~acids~~ acid in a tissue or cellular sample comprising the steps of:

(a) providing a tissue or cellular sample suspected of containing ~~huE3α~~ a human E3α ubiquitin ligase nucleic ~~acids~~ acid;

(b) contacting the tissue or cellular sample with ~~a~~ the reagent according to claim 59 under conditions wherein the reagent will hybridize with ~~huE3α~~ a human E3α ubiquitin ligase nucleic ~~acids~~ acid;

(c) detecting hybridization between ~~huE3α~~ the human E3α ubiquitin ligase nucleic acid in the tissue or cellular sample and the reagent; and

(d) comparing the level of hybridization between the nucleic acid in the tissue or cellular sample and reagent with the level of hybridization between a known concentration of ~~huE3α~~ human E3α ubiquitin ligase nucleic acid and the reagent.

63. (Original) The method of claim 59 wherein said polynucleotide molecule is DNA.

64. (Original) The method of claim 59 wherein said polynucleotide molecule is RNA.

65. (New) An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

(a) the nucleotide sequence as set forth in SEQ ID NO: 18;

(b) a nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 19; and

(c) a nucleotide sequence complementary to either of (a) or (b).